DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

g1994d

One Montvale Avenue
Stoneham, Massachusetts 02180
Tel 781.596.7700
Fax 781.596.7899

September 27, 2001

WARNING LETTER

NWE–40–01W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Augustus Ciulla, President
Gloucester Seafood Display Auction
27–29 Harbor Loop
Gloucester, MA 01930

Dear Mr. Ciulla:

We inspected your firm, located at 27–29 Harbor Loop in Gloucester, MA on August 22 and 23, 2001, and found that you have a serious deviation from the Seafood HACCP regulations (21 CFR Part 123). This deviation causes the bluefish being processed[1] by your firm to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviation was as follows:

- You must implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR § 123.6(b). However, your firm did not follow the monitoring procedure of maintaining harvest vessel records at the critical control point (CCP) of receiving to control the food safety hazard of Scombrotoxin (Histamine) Formation listed in your HACCP plan for bluefish, which is a scombrotoxin-forming species.

[1] Receipt and storage are considered processing steps under the 21 CFR Part 123.

We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to the European Union (EU), if you do not correct this deviation.

We acknowledge the receipt of Barry Sullivan's September 6, 2001 letter responding to the inspectional observations presented to him at the close of the inspection. The control measures you have proposed to deal with the potential hazard of Environmental Chemical Contaminants and Pesticides (for bluefish) should, if adequately implemented, address that issue.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You may wish to include in your response documentation, such as examples of harvest vessel records (or an alternative system of records),[2] or any other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Mark Lookabaugh, Compliance Officer, One (1) Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issue in this letter, please contact Mr. Lookabaugh at ***781.596.7751***.

Sincerely,

Gail T. Costello
Director
New England District

cc:
Barry Sullivan
Gloucester Seafood Display Auction
27–29 Harbor Loop
Gloucester, MA 01930

[2] See page 91, Chapter 7 of *Fish & Fisheries Products Hazards Control Guide*, Third Edition.